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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,254	09/30/2003	Hikaru Matsuda	49288.0800	2567

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EXAMINER

VANIK, DAVID L

ART UNIT PAPER NUMBER

1615

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/675,254

Applicant(s)

MATSUDA ET AL.

Examiner

David L. Vanik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 and 6-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Receipt is acknowledged of the Applicants' Remarks and Amended Claims filed on 2/27/2006.

As a result of Applicants' amendments, the 35 USC §102 rejections over US 6,139,529 ('529) and US 5,647,851 ('851) are hereby **withdrawn**. Additionally, as a result of Applicants' amendments, the 35 USC §112 rejections over US 6,139,529 ('529) and Double Patenting rejections over copending Application No. 10/954639 ('639) are hereby **withdrawn**. However, the 35 USC §102 rejections WO 99/39624 ('624) in view of US 6,673,604 ('604) are hereby **maintained**.

### MAINTAINED REJECTIONS:

The following is a list of maintained rejections:

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6-13, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/39624 ('624) in view of US 6,673,604 ('604).

'624 teach an apparatus for intra-cardiac drug delivery (abstract). The device can deliver a dose of a biological material, such as growth factor, at a determined range of velocity to the heart (abstract and Claim 45). According to '624, the therapeutic agent can be delivered to the heart in a manner that is responsive to physiological signals (Claim 45). On the basis of the physiological signals, it is the examiner's position that one of ordinary skill in the art would have the ability to modulate the rate of drug administration on the basis of the particular application. As such, it is the examiner's position that an ordinary practitioner would have the ability to accelerate or maintain the release of the drug on the basis of evolving physiological signals. It is also the examiner's position that an ordinary practitioner would be able to modify the tip tube of the to between 0.1mm to about 30 mm on the basis of the particular size of the heart or organ to be injected.

'624 does not teach a method of injected cells into an individual at a predetermined rate. However, '604 teach a method of injecting cells into a heart (abstract and Example 1). According to '604, it is advantageous to inject muscle cells into a heart because said muscle cells can aid in cardiac repair (abstract). Because muscle cells, when injected into a heart, can advantageously aid in cardiac repair, one of ordinary skill in the art would have been motivated to inject cardiac cells into a heart in a manner consistent with the disclosure of '624. Based on the teachings of '604, there is a reasonable expectation cardiac cells, when injected into a heart, can aid in cardiac repair. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to inject cells, in a manner consistent with the method advanced by '624, into a heart.

### ***Response to Arguments***

Applicant's arguments filed on 2/27/2006 have been fully considered but they are not persuasive. In response to the 11/25/2005 Non-Final Rejection, Applicant has asserted that '624 teaches a method of "placement" of drugs and not of injection of drugs. Additionally, it is Applicants' assertion that neither '624 nor '604 "teach, advise, or suggest wherein the predetermined range of velocity is at least about 1 ml/min." The examiner respectfully disagrees with these assertions.

Giving the instant claim set the broadest reasonable interpretation, it is the examiner's position that '624 teach a method of injection. Like the instant application,

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the device set forth by '624 has a needle and injects drugs via this needle (see page 15, lines 25-31). In terms of the limitation "wherein the predetermined range of velocity is at least about 1 ml/min," as discussed above, it is the examiner's position that one of ordinary skill in the art would have the ability to modulate the rate of drug administration on the basis of the particular application. This is because, according to '624, the therapeutic agent can be delivered to the heart in a manner that is responsive to physiological signals (Claim 45). Thus, one the basis of said signals, one of ordinary skill in the art would have the ability to modulate the rate of drug administration on the basis of the particular application.

Thus, the examiner respectfully submits that claims 1-4, 6-13, 16-17 are obvious over WO 99/39624 ('624) in view of US 6,673,604 ('604).

#### **NEW REJECTIONS:**

The following is a list of new rejections:

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention. As amended, claim 16 is drawn to a method for “prophylaxis of a heart disease.” This limitation is not specifically enumerated in the instant specification. Although the examiner notes that the instant specification contains the limitation “prophylaxis of a heart” in the instant specification (See paragraphs 0030 and 0046 of Publication US 2005/0070874), this disclosure is insufficient to support the limitation “prophylaxis of a heart disease.”

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Independent Claims 1 and 17 and dependent claims 2-4, 6-13, and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As amended, claims 1 and 17 are drawn to a method of injecting a biological material into a subject at a predetermined range of velocity “wherein the predetermined range of velocity is at least about 1ml/min.” This limitation is not specifically enumerated in the instant specification. Although the examiner notes that the instant specification contains the limitation “velocity is about 1 ml/min to about 20 ml/min” and “velocity is about 1 ml/min to about 10 ml/min” in the

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instant specification (See paragraphs 0019, 0026, and 0027 of Publication US 2005/0070874), the disclosure is insufficient to support the limitation "wherein the predetermined range of velocity is at least about 1ml/min."

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Independent Claims 1 and 17 and dependent claims 2-4, 7-13, and 16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of injecting a liquid drug at "a velocity is about 1 ml/min to about 20 ml/min" or "a velocity is about 1 ml/min to about 10 ml/min", does not reasonably provide enablement for a method of injecting a biological material into a subject at a predetermined range of velocity "wherein the predetermined range of velocity is at least about 1ml/min." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

As written, given the claims their broadest reasonable interpretation, a method of injecting a biological material into a subject at a predetermined range of velocity "wherein the predetermined range of velocity is at least about 1ml/min" implies that the predetermined range of velocity can be anything over "about 1ml/min" (for example, 1000ml/min). The examiner respectfully submits that the instant specification teaches



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against this limitation. Specifically, as set forth in the instant specification, the range of the velocity has a lower and an upper limit. The range of the velocity is about 1 ml/min to about 20 ml/min or about 1 ml/min to about 10 ml/min. Consistent with the instant specification, the limitation "wherein the predetermined range of velocity is at least about 1ml/min" is not enabled and would subject one of ordinary skill in the art with an undue amount of experimentation in order to practice the invention commensurate in scope with the claims.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 5-13, and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13, and 16 of copending Application No. 10/954,639 ('639). Although the conflicting claims are not identical, they are not patentably distinct from each other because, like the instant application, '639 claim a method for injecting a liquid drug containing a biological material into a subject at a predetermined range of velocity (Claim 1 of '639). '639 also claim a method for injecting a liquid drug containing a biological material into a subject at an accelerated range (Claim 6 of '639). The diameter of the injector and biological materials are also the same in '639 and the instant claims 1-13, 16-17 (See Claims 2-5, 7-13, and 16-17 of '639).

'639 does not specifically claim a method of injecting a biological material into a subject at a predetermined range of velocity "wherein the predetermined range of velocity is at least about 1ml/min." However, as set forth in claim 5 of '639, the velocity range "is about 1 ml/min to about 10 ml/min." Given that claim 5 includes the limitation "about 1ml/min," one of ordinary skill in the art at the time the invention was made would have been motivated to claim a method of injecting a biological material into a subject at a predetermined range of velocity "wherein the predetermined range of velocity is at least about 1ml/min." This is because, as set forth in claim 5, '639 claims a velocity of over "about 1ml/min" – "about 1 ml/min to about 10 ml/min."

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-11 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,690,618 ('618).

'618 disclose electronic syringe compositions capable of delivering active agents, such as anesthetics, insulin, vitamins, minerals, pharmaceuticals, and imaging dyes to individuals (abstract and column 8, lines 61-64). Like the instant claim set, '618 teach a method delivering the active agents at a predetermined rate that may include acceleration/deceleration patterns (column 8, lines 45-54). Depending on the type of syringe used, the flow rate and needle exit velocity can be varied (column 6, lines 14-42). For example, when a 30 gauge needle is used (an inner diameter of 0.25 mm – See US 6,273,715; column 4, lines 59-67), the flow rate is 0.12 ml/s or 7.2 ml/minute (Table 1). This flow rate is well within the range of the instant claim 1. Given the claims their broadest reasonable interpretation, “at least about 1ml/min” is being interpreted as any amount over “about 1 ml/min.”

The claims are therefore anticipated by US 5,690,618 ('618):

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-13 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,690,618 ('618) in view of US 6,673,604 ('604).

The teachings of '618 are set forth above. '618 teaches a method of injecting a wide-variety of pharmaceutical substances into subjects at a predetermined rate of at least about 1 ml/min. However, '618 does not specifically teach injecting cell-based pharmaceuticals into the heart of a subject.

However, '604 teach a method of injecting cells into a heart (abstract and Example 1). According to '604, it is advantageous to inject muscle cells into a heart because said muscle cells can aid in cardiac repair (abstract). Because muscle cells, when injected into a heart, can advantageously aid in cardiac repair, one of ordinary skill in the art would have been motivated to inject cardiac cells into a heart in a manner

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consistent with the disclosure of '618. Based on the teachings of '604, there is a reasonable expectation cardiac cells, when injected into a heart, can aid in cardiac repair. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to inject cells, in a manner consistent with the method advanced by '618, into a heart.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

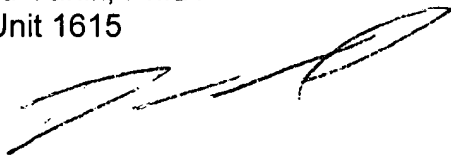
***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.  
Art Unit 1615



5/8/06



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